

REMARKS/ARGUMENTS

Reconsideration of the present application, as amended, is respectfully requested.

A. STATUS OF THE CLAIMS

As a result of the present amendment, claims 1, 3 and 5-9 are presented in the case for continued prosecution. The subject matter of claim 2 is now presented in claim 1. Support for the amendment to claim 5 can be found, for example, on page 4, line 4 of the specification.

B. DRAWINGS

Applicants submit herewith amended Figure 2 showing the required correction for consideration by the Examiner. It is noted that Figure 2 corresponds to Table 1 in the specification. The portion of the specification which discusses Table 1 has been clarified without entering new matter.

C. CLAIM OBJECTIONS

The Examiner objections to claim 1 and claim 2 have been addressed by the amendment to these claims presented herewith.

D. REJECTIONS UNDER 35 U.S.C. § 112, FIRST PARAGRAPH

1. At page 4 of the Office Action, the Examiner has rejected claim 4 under 35 U.S.C. § 112, first paragraph, alleging that the claim fails to comply with the written description requirement and contains subject matter which was not sufficiently described in the specification. In response thereto, Applicant has cancelled claim 4, thereby rendering the rejection moot.

2. Non-enablement

At page 4 of the office action, the Examiner has rejected claims 5-9 and 10, alleging that the claims fail to comply with the enablement requirement. In response thereto, Applicant

submits that the amendment to claim 5 as well as that made to claim 1, (the claim from which each of the rejected claims depends) render this rejection moot with regard to non-enablement for claims 5-9. Claim 10 has been cancelled. There is no need to provide a definition of alopecia in the specification when the meaning of the term is well understood by those of ordinary skill. The claims are urged to be in proper form and satisfy all requirements of 35 U.S.C. §112.

In the event that the Examiner maintains the position of non-enablement even after consideration of the amendment to claim 1, Applicant respectfully asserts that a *prima facie* case of non-enablement has not been established by the Examiner. The Examiner has not provided any cogent reason why the skilled artisan could not carry out the claimed process or make and use the invention as claimed. It is urged that there is no reason to question the objective enablement provided by the disclosure in the application, see *Ex parte Volheim, et al.* (POBA 1975) 191 USPQ 407, 408. It is not a function of the claims to specifically exclude possible inoperative substances. *In re Dinh-Nguyen et al.* (CCPA 1974) 181 USPQ 46. The initial burden is on the Examiner to provide evidence why the skilled artisan would not be enabled to practice the claimed invention throughout the entire scope of the claims. *In re Wands* 8 USPQ2d 1400 (Fed.Cir. 1988).

Further guidance on these issues has been provided by the courts. For example, in *General Electric Co. v. Brenner*, 159 USPQ 335, 337 (D.C. Cir. 1968) it was held

"...[The specification] need only be reasonable with respect to the art involved; they need not inform the layman nor disclose what the skilled already possess. They need not describe the conventional... The intricacies need not be detailed ad absurdum." The CAFC in *Lindemann Maschinenfabrik GmbH v. American Hoist & Derrick Co.*, 221 USPQ 481, 489 (Fed. Cir. 1984) indicated: "...the question is whether the disclosure is sufficient to enable those skilled in the art to practice the claimed invention, hence the specification need not disclose what is well known in the art." The CCPA in *In re Angstadt*, 190 USPQ 214, 219 (C.C.P.A. 1976), noted that "...the PTO has the burden of giving reasons, supported by the record as a whole, why the specification is not enabling ...". The PTO should be concerned with the truth (accuracy) of a generic term, not its breadth. *In re Marzocchi et al.*, (CCPA 1971) 439 F2d 220, 169 USPQ 367. Applicant asserts that the claims describe a composition and method for treating alopecia. The composition is to be administered to the affected area which requires treatment. It is

important to note that Applicant is not claiming that (3- β -HSOR) and (17- α -HSOR) act as antiandrogens by changing testosterone into 4-androsterone-3,17 dione. Instead, the present application seeks to claim Applicant's discovery that a pool of (3- β -HSOR) and (17- α -HSOR) can transform DHT into chemical entities which do not harm hair follicles (bulbs).

On page 6 of the office action, the Examiner raises issues relating to Figure 3 and the formazan assay. Applicant wishes to clarify the fact that dehydrogenase activity is higher in Control A since there is no chemical entity to harm the hair bulbs. The effect of DHT on dehydrogenase activity is clear in B. Dehydrogenase activity is very low because the DHT has killed the majority of the hair bulbs. C shows that NADH (not NAD as claimed herein) coenzyme is useless to (3- β -HSOR) and (17- α -HSOR), because DHT activity is not lowered significantly as compared to B. The role of (3- β -HSOR) and (17- α -HSOR) with NAD coenzyme appears clearly in D where dehydrogenase levels almost reach control levels. Objective enablement has been provided. Reconsideration and removal of the rejection is therefore proper and the same is urged by Applicants.

E. CLAIM REJECTIONS UNDER 35 U.S.C. §112, SECOND PARAGRAPH

The Examiner has rejected claims 1, 3-8 and 10 as being indefinite. In response thereto, Applicant has amended claim 1 (claims 3 and 5-8 are dependent thereon). Claim 10 has been cancelled. It is respectfully submitted that the claims are now in proper form and that the rejection can be removed.

Claim 3 has been amended so as to provide the proper antecedent bases noted by the Examiner. With regard to claim 5, it is noted that the amount which is sufficient to achieve the desired result is purposely claimed broadly due to the cosmetic and pharmaceutical uses for the composition. As will be appreciated by the Examiner, the degree of alopecia in any given patient will be unique, varying from patient to patient. Therefore, the amount of the composition required to be applied to the affected areas to treat the alopecia must be calibrated by one of ordinary skill prior to treatment.

F. REJECTIONS UNDER 35 U.S.C. § 103

The Examiner has rejected the subject matter of claim 1, 3-8 as being obvious over WO 01/66702 in view of U.S. Patent No. 5,514,672 and 6,773,776. The Examiner has not rejected

the subject matter of claim 2 under this section of the patent statute. Claim 1 has been amended to include the subject matter of claim 2 therein, which renders the rejection moot. It is respectfully urged that all claims are free of prior art.

G. FEES

This response is being filed within the shortened period for response. No further fee is believed to be due. If, on the other hand, it is determined that any further fees are due or any overpayment has been made, the Assistant Commissioner is hereby authorized to debit or credit such sum to deposit account 02-2275. Pursuant to 37 C.F.R. 1.136(a)(3), please treat this and any concurrent or future reply in this application that requires a petition for an extension of time for its timely submission as incorporating a petition for extension of time for the appropriate length of time. The fee associated therewith is to be charged to Deposit Account No. 02-2275.

H. CONCLUSION

In view of the actions taken and arguments presented, it is respectfully submitted that each and every one of the matters raised by the Examiner have been addressed by the present amendment and that the present application is now in condition for allowance.

An early and favorable action on the merits is earnestly solicited.

Respectfully submitted,

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AMENDMENTS TO THE DRAWINGS:

The attached sheet of drawing replaces the original Figure 2. The changes required by the Examiner have been made.

Attachment: Replacement Sheet